

UNITED STATES DISTRICT COURT

DISTRICT OF SOUTH DAKOTA

WESTERN DIVISION

CRAIG KENDALL,	)	CIV. 05-5066-KES
	)	
Plaintiff,	)	
	)	
vs.	)	MEMORANDUM OPINION
	)	AND ORDER
BAUSCH & LOMB, INCORPORATED	)	
and LASER VISION CENTERS, INC.,	)	
	)	
Defendants.	)	

Defendant Bausch & Lomb, Incorporated (B&L) moves for summary judgment. Docket 181. B&L also moves to strike. Docket 241. Plaintiff, Craig Kendall, has fully responded to the motions, and the matters are now ripe for disposition. The motion to strike is denied, and the motion for summary judgment is granted in part and denied in part.

**FACTUAL BACKGROUND**

Following are the relevant facts construed in the light most favorable to Kendall, the non-moving party:

On December 10, 2002, Kendall underwent LASIK surgery to correct his vision. Dr. John Bormes performed Kendall's surgery at Ophthalmology Associates in Aberdeen, South Dakota. During LASIK surgery, a device called a microkeratome applies suction to the patient's cornea while a motorized blade cuts a flap of the corneal tissue. The surgeon then uses a laser to remove corneal tissue, after which the flap is replaced. Dr. Bormes contracted with defendant Laser Vision Centers, Inc. (LVCI) to supply LASIK equipment,

including AccuGlide blades and personnel to assist during surgeries. For Kendall's surgery, Dr. Bormes used a microkeratome with an AccuGlide blade from manufacturing lot #517984, which was designed, manufactured, packaged, sold, and distributed by B&L.

LVCi technician Elaine Shotwell assisted Dr. Bormes during Kendall's surgery. Neither Dr. Bormes nor Shotwell recall anything about Kendall's procedure, but it is believed that no remarkable complications arose during the surgery. Docket 211, Plaintiff's Statement of Material Facts (PSMF), ¶ 3. It is Shotwell's normal practice to inspect the AccuGlide blade under a microscope to ensure that there are no visible defects and to reject the blade if it appears abnormal or defective. Additionally, Dr. Bormes typically conducts a visual inspection of the blade before using it.

After the surgery, Kendall developed diffuse lamellar keratitis (DLK) in both of his eyes. DLK is a inflammatory condition of the interface of the corneal flap that may be a complication of LASIK surgery. The causes of DLK are not completely understood in the medical community. Incidences of DLK often cannot be traced to one cause, and studies have linked it to many different causes that arise over the course of LASIK and other eye surgeries. This condition is widely-known among individuals who perform LASIK surgery, and it is standard procedure to watch for the development for DLK during post-operative check-ups.

Dr. Bormes performed eleven LASIK surgeries on December 10, 2002. PSMF ¶ 4. All of Dr. Bormes' patients from that day whose surgery involved a blade from lot #517984 developed DLK. Id. ¶ 8. Prior to this date, none of Dr. Bormes' LASIK patients had contracted DLK. Id. ¶ 5.

DLK is often treated effectively by anti-inflammatory drops. But the anti-inflammatory drops prescribed for Kendall did not successfully treat his DLK. As a result of the DLK, Kendall required a further procedure called a flap lift, after which he developed further complications, including striae, epithelial ingrowth, and irregular astigmatism. PSMF ¶ 9. Kendall has undergone additional surgeries to address these complications, and he has sustained permanent injury that he claims stems from the DLK. Id. ¶ 10.

Prior to November 2002, B&L had received complaints of post-operative DLK in less than one percent of procedures which used AccuGlide blades. During the 12 months prior to November 2002, B&L had received 53 reports of DLK and 580,000 blades were shipped over that time. Customer complaints to B&L are typically made by the doctor who used the blade or by a B&L customer service or sales representative.

Between November 2002 and May 2003, B&L received an increased number of reports of DLK occurrences. In particular, reports of DLK occurrence from surgeries involving blades in lot number #517984 were exceptionally high. Each blade lot, including lot #517984, includes 1400 blades. The first complaint of DLK associated with lot #517984 was received

by Juli Moore, a Product Surveillance Officer with B&L, on November 18, 2002. On November 25, 2002, Moore notified a B&L Quality Control Engineer that Product Surveillance had received reports of 37 incidences of DLK from three different facilities which had used blades from lot #517984. PSMF ¶ 15. On November 29, 2002, Product Surveillance received a report from a fourth facility of four instances of DLK in surgeries that had involved blades from lot #517984; Moore notified Parker of this fourth report on December 2, 2002. Id. at ¶ 17. Quality Control Manager Tom Brennan was also notified about Product Surveillance's reports on December 2, 2002. By that date, B&L had been informed about 42 cases of DLK occurrences in surgeries associated with blade lot #517984. In response, Brennan called for a containment meeting. That same day, B&L quarantined the remaining blades in lot #517984 which had not yet been shipped. Daniel Newhart did not set up a containment meeting until December 9, 2002, even though it was his regular practice to set up a containment meeting within 24 hours of notification of a potential problem. By December 9, 2002, B&L had received 79 complaints of DLK from seven different surgery sites who used blades from lot #517984.

At the December 9, 2002, containment meeting, those conducting the investigation behind the DLK occurrences were operating under a general assumption that DLK was the result of residue or debris on the blades; however, their testing was inconclusive, and no causal factor was identified. No immediate action was taken after the December 9 containment meeting

regarding blades in lot #517984 or in any other lot. On December 10, 2002, however, LVCI initiated its own recall of the blades in lot #517984. That same day, December 10, 2002, Dr. Bormes performed Kendall's LASIK surgery using a blade from lot #517984. B&L held containment meetings on December 11 and 12, and on December 13, B&L voluntarily recalled lots #517984 and #517985. Ultimately, B&L received 281 DLK complaints that involved blades associated with lot #517984 from over fifteen different locations. PSMF ¶ 39.

B&L did not receive customer complaints of DLK regarding all distributed blades from lot #517984. Additionally, the incidences of DLK increased during this time period for several lots of blades, not just lot #517984, with some lots reporting between 41 to 89 cases of DLK. B&L conducted a number of studies to determine whether the blades in lot #517984 were defective and tested for every contaminant suggested by medical literature as a possible cause of DLK. The investigation did not provide a conclusive answer regarding the causation of the DLK. Additionally, the blade used in Kendall's surgery was not tested after his DLK diagnosis, and that blade has since been discarded without testing. No tests were performed on any of the instruments used in Kendall's procedure or on the autoclave, a device which sterilized the equipment.

After the increased reports of DLK occurrence, B&L took a number of steps to improve its blade manufacturing process. The rates of DLK after these measures were taken were comparable to the rates reported prior to November 2002.

## **DISCUSSION**

### **I. Motion to Strike**

In opposition to B&L's motion for summary judgment, Kendall filed, among other things, a response to B&L's statement of material facts, Docket 210, as well as his own statement of material facts, Docket 211. See also Docket 212, 213 (affidavits in support of statement of material facts). B&L then filed a response to Kendall's statement of material facts as well as objections to exhibits submitted in support of the statement of material facts. Docket 221. In response, Kendall filed a reply to B&L's response and objections, arguing that he properly submitted his statement of material facts and that his exhibits are properly authenticated. Docket 233. It is that final reply that B&L seeks to strike as improper. Docket 241. For the reasons stated below, the motion to strike is denied as moot.

First, the court addresses B&L's opposition to Kendall's statement of material facts. While not a formal motion to strike, B&L argues in its reply that Kendall improperly submitted his own statement of material facts in Docket 211, contending that "the Local Rules do not contemplate the submission of such a lengthy, argumentative submission by a party *opposing* a motion for summary judgment." See Docket 221. Asserting that the allegations in Kendall's statement of material facts (PSMF) are duplicative, irrelevant, and lengthy, B&L asks that this filing be stricken. Id. at 1-2.

The court disagrees with B&L that Kendall's statement of material facts was an improper filing. While Local Rule 56.1 does not explicitly require a party opposing a summary judgment motion to file its own separate statement of material facts, it does state that a party "shall identify any material facts as to which it is contended that there exists a genuine material issue to be tried." D.S.D. CIV. LR 56.1(B). That is precisely what Kendall did in his statement of material facts. Additionally, such submissions of material facts from parties opposing a motion for summary judgment are not uncommon in the District of South Dakota. See Terrell v. Dooley, 2008 WL 1957847, \*1 (D.S.D. May 2, 2008); Statler v. Buffalo-Bodega Complex, Inc., 2007 WL 320959, \*1 (D.S.D. Jan. 30, 2007). Finally, "the district court has considerable leeway in the application of its local rules." Silberstein v. I.R.S., 16 F.3d 858, 860 (8th Cir. 1994). Because the court is to consider the facts in the light most favorable to the nonmoving party in its consideration of a motion for summary judgment, it does not believe that it was improper for Kendall to submit his own statement of material facts, especially given that both parties have submitted voluminous filings to the court regarding the disputed facts in this case. For these reasons, the court denies B&L's request to strike Kendall's statement of material facts.

B&L also objects to the exhibits filed by Kendall, presumably in Dockets 212, 213, and 217, in support of his statement of material facts. See Docket 221, page 3. B&L argues that eight of the exhibits should be stricken because they are entire deposition transcripts in violation of Local Rule 7.3, and

because the exhibits are not properly authenticated. Id. at 3. B&L also submits numerous specific evidentiary objections to portions of the exhibits. Id. at 3-4. Both parties in this case have filed ample documents in support of their versions of the facts. See Docket 200.

Local Rule 7.3 states: “A party must submit as exhibits or attachments only those excerpts of the referenced document that are directly germane to the matter under consideration by the Court. . . . Highlighting relevant portions is encouraged.” D.S.D. CIV. LR 7.3. Local Rule 56.1(C) states that documentary evidence related to a motion for summary judgment “shall be submitted with proper highlighting as encouraged by LR 7.3.” As discussed above, the court has significant leeway in enforcing its own rules, and this would seem to be especially true when the rules in question are designed for the convenience of the court. Therefore, the motion to strike the exhibits is denied.

B&L also states that these exhibits should not be considered because they are inadmissible and are not authenticated by an affidavit. Docket 221, page 3. Again, while the court would prefer a pared-down version of the exhibits filed by Kendall in Dockets 212, 213, and 217, it believes that it may properly consider these exhibits under Federal Rule of Civil Procedure 56(c), which provides that the court is to examine the pleadings as well as “discovery and disclosure materials on file” and affidavits to determine the propriety of summary judgment. As the exhibits consist of discovery and disclosure



materials, the court believes that it may properly consider such in deciding the motions before it, and B&L has given the court no reason to think otherwise.

Finally, B&L lists many specific evidentiary objections to several exhibits filed in Docket 217. Docket 221, page 3-4. A party opposing a motion for summary judgment must show that there is a genuine factual dispute by setting out facts “that would be admissible in evidence.” Fed. R. Civ. P. 56(e)(1). The court declines to rule on each of the objections at this time. Instead, it will broadly consider B&L’s objections as discussed in Docket 221 and the general admissibility of the exhibits discussed therein in making its determination regarding summary judgment.

The court finds that Kendall properly submitted his own statement of material facts and properly filed exhibits in Docket 212, 213, and 217. Accordingly, the court need not consider Kendall’s sur-reply in Docket 233, and B&L’s motion to strike Docket 233 is now moot.

## **II. Motion for Summary Judgment**

Summary judgment is proper “if the pleadings, depositions, answers to interrogatories, and admissions on file, together with the affidavits, if any, show that there is no genuine issue as to any material fact and that the moving party is entitled to a judgment as a matter of law.” Fed. R. Civ. P. 56(c). In determining whether summary judgment should issue, the facts and inferences from those facts are viewed in the light most favorable to the nonmoving party, and the burden is placed on the moving party to establish both the absence of

a genuine issue of material fact and that such party is entitled to judgment as a matter of law. Id.; Matsushita Elec. Indus. Co. v. Zenith Radio Corp., 475 U.S. 574, 586, 106 S. Ct. 1348, 89 L. Ed. 2d 538 (1986). Once the moving party has met this burden, the nonmoving party may not rest on the allegations in the pleadings, but by affidavit or other evidence must set forth specific facts showing that a genuine issue of material fact exists. Fed. R. Civ. P. 56(e)(2). In determining whether a genuine issue of material fact exists, the court views the evidence presented based upon which party has the burden of proof under the applicable substantive law. Anderson v. Liberty Lobby, Inc., 477 U.S. 242, 252, 106 S. Ct. 2505, 91 L. Ed. 2d 202 (1986).

#### **A. Preliminary Evidentiary Disputes**

In its motion for summary judgment, B&L alleges that much of the evidence that Kendall intends to use to prove the existence of a defective blade is inadmissible. Docket 182, page 5. B&L anticipates four different ways Kendall will attempt to prove the existence of a defect: evidence of customer complaints, evidence of B&L's blade recall, evidence of other subsequent corrective measures, and potential expert testimony of Dr. Hardten. B&L argues that "[s]uch inadmissible and/or unreliable evidence is legally insufficient to support his case." Id. In his response opposing summary judgment, Kendall admits that his case is based on circumstantial evidence, but he maintains that this fact "is no barrier to the maintenance of this action." Docket 218, page 6.

The court notes that, under South Dakota law, a plaintiff in a strict products liability action may prove the presence of a defect through circumstantial evidence. Jahnig v. Coisman, 283 N.W.2d 557, 560 (S.D. 1979). "No specific defect need be shown if the evidence, direct or circumstantial, permits the inference that the accident was caused by a defect." Shaffer v. Honeywell, Inc., 249 N.W.2d 251, 256 (S.D. 1976) (involving both strict liability and negligence claims). Moreover, "causation may be established by circumstantial evidence where that evidence establishes by a preponderance, the probability that the accident was caused by a defect." Id.

The parties appear to disagree over the framing of the disputed evidence. B&L contends that evidence of the customer complaints, evidence of B&L's blade recall and other subsequent corrective measures, and potential expert testimony by Dr. Hardten goes primarily to Kendall's proof of the existence of a defect. See Docket 182, pages 5-18. But Kendall views this evidence instead as admissible to prove causation. Docket 218, pages 5-14.

As discussed below, each of Kendall's strict liability claims requires him to prove causation as well as the existence of a defect. See Brech v. J.C.Penney Co., Inc., 698 F.2d 332, 333-34 (8th Cir. 1983); Restatement (Second) Torts § 402A. Evidence of customer complaints, remedial measures taken by B&L, and expert testimony is relevant to establish both of these essential elements. Based on the facts known to the court, some or all of this disputed evidence

must be admissible for Kendall to prove the necessary elements of his strict liability claims and to avoid summary judgment. Accordingly, the court must determine the admissibility of each of these areas of evidence before it draws a conclusion regarding the presence of a genuine dispute of material fact.

**1. Customer Complaints Against Blade Lot #517984**

As discussed above, B&L received many complaints regarding DLK occurrence in surgeries using blades from lot #517984. B&L argues that evidence of these complaints is inadmissible hearsay. Kendall states that he does not plan “to rely upon the opinions of the reporting physicians that a blade from lot #517984 caused DLK in their patient. Rather, Kendall offers the evidence to show that (1) surgery was performed with a blade from lot #517984 and, (2) the patient was subsequently diagnosed with DLK.” Docket 218, page 12. Kendall argues both that B&L’s records of customer complaints are admissible under Federal Rule of Evidence 803(6) as business records, and that he intends to present nonhearsay evidence of the complaints in the form of deposition testimony from physicians who reported DLK occurrence in their patients following the use of blades from lot #517984. *Id.* at 12-13.

The court need not determine at this time the evidentiary question of whether or not B&L's own records of customer complaints related to blade lot #517984 are admissible. Kendall has stated that he intends to offer nonhearsay evidence regarding these complaints. Therefore, even if the court were to rule prior to trial that B&L's records do not fall within a business

records exception to the hearsay rule, Kendall may still be able to present nonhearsay evidence regarding the occurrences of DLK in blade lot #517984 as reported to B&L. Additionally, the court can consider the nonhearsay testimony regarding customer complaints for the truth of the matter asserted –that DLK occurred when blades from lot #517984 were used.<sup>1</sup>

B&L argues that the customer complaints are not admissible because they are not substantially similar to the facts alleged in the complaint. Docket 222, pages 6-7.

Evidence of prior incidents or accidents is admissible in a products liability case to prove “the defendant's notice of defects, the defendant's ability to correct known defects, the magnitude of the danger, the product's lack of safety for intended uses, or causation.” The evidence is only admissible, however, if the prior incidents are “substantially similar” to the facts of this case. The prior incidents “must be sufficiently similar in time, place, or circumstance to be probative.”

Sheesley v. Cessna Aircraft Co., 2006 WL 3042793, \*11 (D.S.D. Oct. 24, 2006) (citing Lovett ex rel. Lovett v. Union Pac. R.R., 201 F.3d 1074, 1080 (8th Cir. 2000) and First Sec. Bank v. Union Pac. R.R., 152 F.3d 877, 879 (8th Cir.

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<sup>1</sup> In its reply brief, B&L argues that Kendall cannot use customer complaints to prove notice; however, this is only an issue if the complaints come in the form of hearsay. See Docket 222, pages 6-7; see also United States v. Singer, 687 F.2d 1135, 1147 (8th Cir. 1982) (stating that the purpose of the hearsay rules is to exclude “declarations whose veracity cannot be tested by cross-examination”); see also Olson v. Ford Motor Co., 410 F. Supp. 2d 855, 862-63 (D.N.D. 2006) (admitting hearsay evidence of customer complaints to prove notice in a failure to warn case). Kendall has already stated that he intends to offer nonhearsay evidence on this question, and therefore, the court need not determine whether a hearsay exception applies.

1998)). B&L argues that Kendall cannot establish the requisite similarity. Construing the facts in the light most favorable to Kendall, the nonmoving party, the court believes that testimony from doctors who used blades from lot #517984 and whose patients developed DLK may be admissible, if Kendall lays the proper foundation demonstrating that the circumstances around the different surgeries were indeed substantially similar. See Lewy v. Remington Arms Co., Inc., 836 F.2d 1104, 1108 (8th Cir. 1988); Sheesley, 2006 WL 3042793 at \*11 (stating that “plaintiffs should have the opportunity to lay foundation to establish that the incidents . . . are factually similar”); see also Olson, 410 F. Supp. 2d at 863 (admitting some customer complaints where they were substantially similar in time, place, and circumstance to the accident in question). Therefore, the court will consider for purposes of the summary judgment motion the customer complaints as evidence of similar incidents, which may be used to prove the existence of a defect, causation, and foreseeability of the injury.

## **2. Subsequent Remedial Measures**

B&L next argues that Kendall cannot prove the existence of a defect by introducing evidence of its voluntary recall of certain blade lots or evidence of changes it made to the blade manufacturing process after Kendall's surgery. Docket 182, pages 8-11. Evidence of subsequent remedial measures is barred by Federal Rule of Evidence 407, contends B&L. Id. at 8-9. In response, Kendall argues that “Rule 407 does not preclude the admission of subsequent

remedial measures on grounds other than to prove culpability,” and such evidence can be used to prove causation “if that is in controversy.” Docket 218, pages 13-14 (citing Brazos River Authority v. GE Ionics, Inc., 469 F.3d 416, 429 (5th Cir. 2006)). Kendall also states that an exception to Rule 407 may be proper “where the defendant attempts to make offensive use of the exclusion of the evidence.” Id. at 13. Kendall goes on to state that Rule 407 may permit evidence of subsequent measures “offered for the purposes of impeachment” and that Rule 407 “does not bar test results and investigative findings.” Id. at 14.

Federal Rule of Evidence 407 states as follows:

When, after an injury or harm allegedly caused by an event, measures are taken that, if taken previously, would have made the injury or harm less likely to occur, evidence of the subsequent measures is not admissible to prove negligence, culpable conduct, a defect in a product, a defect in a product's design, or a need for a warning or instruction. This rule does not require the exclusion of evidence of subsequent measures when offered for another purpose, such as proving ownership, control, or feasibility of precautionary measures, if controverted, or impeachment.

This rule recognizes “a social policy of encouraging people to take, or at least not discouraging them from taking, steps in furtherance of added safety.”

Comment to Rule 407 (1972); 23 Charles Alan Wright & Kenneth W. Graham, Jr., FEDERAL PRACTICE AND PROCEDURE § 5282.

Rule 407 only discusses subsequent measures taken after the injury has occurred, and it does not preclude evidence of measures taken after manufacture of the item but prior to the accident. Bogosian v. Mercedes-Benz

of North America, Inc., 104 F.3d 472, 481 (1st Cir. 1997); Huffman v. Caterpillar Tractor Co., 908 F.2d 1470, 1481 (10th Cir. 1990) (stating that “event” in the rule applies to the time of the injury to the plaintiff, not to the creation of the hazard); Chase v. General Motors Corp., 856 F.2d 17, 22 (4th Cir. 1988). Therefore, B&L's conduct in the days prior to Kendall's surgery—conduct which this court believes is directly relevant to B&L's culpability on the claims—is not covered by Rule 407 and therefore appears, at this time, to be admissible.

With regard to the measures taken by B&L after December 10, 2002, the court finds that evidence of this post-accident conduct is prohibited by Federal Rule of Evidence 407 to prove B&L's negligence, its culpable conduct, or the existence of a defective product. This inadmissible post-accident conduct includes B&L's voluntary recall of the blades in lot #517984 and other lots, as well as changes it made in the blade manufacturing process. See J.B. Hunt Transport, Inc. v. General Motors Corp., 243 F.3d 441, 445 (8th Cir. 2001) (stating that “a company's postaccident design change is inadmissible to prove fault”); First Sec. Bank v. Union Pacific Railroad Co., 152 F.3d at 881 (affirming exclusion of memorandum involving a change in policy after the accident); Hammes v. Yamaha Motor Corp., 2006 WL 1195907, \*11 (D. Minn. May 4, 2006) (stating that evidence of a recall “is a subsequent remedial measure and would not be admissible to prove the existence of a product defect”). Admitting this evidence violates the policy of Rule 407 to avoid punishing actors who take



steps after an accident to improve safety. See Minter v. Prime Equipment Co., 451 F.3d 1196, 1211-12 (10th Cir. 2006).

Kendall argues correctly, however, that evidence of subsequent measures may be admissible for impeachment, should such a situation at trial arise. See Fed. R. Evid. 407 (explicitly stating that the rule does not require the exclusion of evidence for impeachment purposes). But this only occurs if B&L opens the door by contesting “ownership, control, or feasibility of precautionary measures.” Id. Kendall, as a plaintiff with the burden of proof, must demonstrate that he has substantive evidence to make a prima facie case to defeat the motion for summary judgment, and he cannot rely on the possibility of impeachment evidence to demonstrate that there is a dispute of material fact. See 10A CHARLES ALAN WRIGHT, ARTHUR R. MILLER, AND MARY KAY KANE, FEDERAL PRACTICE AND PROCEDURE § 1717 (3d ed. 1998) (stating that a party opposing a summary judgment motion “is not entitled to a trial on the basis of a hope that he can produce some evidence at that time”); see also Firemen's Fund Ins. Co. v. Thien, 8 F.3d 1307, 1311 (8th Cir. 1993). Whether or not this evidence of B&L’s subsequent policy changes may be admissible at trial as impeachment evidence is not relevant to the appropriateness of summary judgment which this court is now considering.

Kendall also contends that evidence of remedial measures may be admissible as substantive evidence to prove causation, because causation is “another purpose” discussed in Rule 407, citing Brazos River Auth. v. GE

Ionics, Inc., 469 F.3d 416 (5th Cir. 2006)). Brazos is distinguishable from this case, however, because that case involved claims for breaches of warranty. Unlike suits involving claims of negligence or a defective product, stated the Fifth Circuit, warranty claims do not require evidence of an “injury or harm” as referred to in Rule 407, but instead concern “the failure of the product to work as warranted.” Brazos, 469 F.3d at 429. For this reason, the Fifth Circuit concluded that Rule 407 is inapplicable to warranty claims. Id.

Even if this proposition about warranty claims were adopted by the Eighth Circuit, this court still believes that it would be unable to admit evidence of subsequent remedial measures on Kendall’s non-warranty claims, which clearly require proof of a specific injury or harm. The court will not read into Rule 407 an exception for causation, especially in cases where jurors may easily draw inferences from the post-accident remedial measures to a party’s negligence or the defectiveness of a product. See Werner v. Upjohn Co., Inc., 628 F.2d 848, 853-54, 856 (4th Cir. 1980) (reversing admission of remedial measures to prove feasibility, when instead the evidence suggested improper inferences regarding defendant’s negligent conduct). To do so would seem to be in direct conflict with the explicit language of Rule 407. Thus, the court does not believe that evidence of B&L’s subsequent remedial measures will be admissible at trial, and the court will not rely on it here in its determination regarding the motion for summary judgment.

Finally, Kendall states correctly that “Rule 407 does not bar test results and investigative findings.” Docket 218, page 14. The court does not believe that test results and investigative findings, even when completed subsequent to Kendall's accident, can be considered “remedial” under Rule 407; therefore, they are admissible and may be considered by this court. See Brazos River Auth., 469 F.3d at 431 (citing 2 Weinstein et al. Federal Evidence (2d ed. 1997) § 407.06[1]); Prentiss & Carlisle Co., Inc. v. Koehring-Waterous Div. of Timberjack, Inc., 972 F.2d 6, 10 (1st Cir. 1992) (stating that Rule 407 prohibits evidence of subsequent measures “not evidence of a party's analysis of its product” even if that analysis may result in remedial measures); cf. Complaint of Consolidation Coal Co., 123 F.3d 126, 136 (3d Cir. 1997) (stating that “there is authority supporting the exclusion of evidence of post-accident investigations under Rule 407”). Therefore, the court will consider B&L's post-accident testing of the blades and of its manufacturing processes in its summary judgment determination.

### **3. Expert Testimony Regarding Differential Diagnosis**

B&L next argues that Kendall is unable to prove the presence of a defect based on his expert's differential diagnosis. B&L argues that Dr. Hardten's differential diagnosis is insufficient in that he has failed to rule out other potential causes, and, therefore, “the methodology underlying the opinions as to blade defect and causation are fundamentally flawed and thus inherently unreliable.” Id. at 12. Consequently, argues B&L, Hardten's expert opinion

must be excluded under Daubert v. Merrell Dow Pharmaceuticals, Inc., 509 U.S. 579, 597 (1993) and Federal Rule of Evidence 702. In response, Kendall argues that Hardten's differential diagnosis is “presumptively admissible” and that any faults in his analysis go to the weight of his testimony and not its admissibility. In its reply, B&L submits additional arguments regarding Hardten's testimony, contending that it will prove confusing to the jury, that it is unreliable as a matter of law, that it would be superfluous to the jury's own understanding, and that it is improperly based on case studies.

It appears to the court that expert testimony is essential to at least some of Kendall's claims. For example, claims alleging negligence in a products liability action will ordinarily require expert testimony, often to demonstrate defendant's negligent conduct as well as causation. See Burley v. Kytec Innovative Sports Equip. Inc., 737 N.W.2d 397, 407 (S.D. 2007). Products liability claims based on negligence require the plaintiff to prove that the defendant failed to act in a reasonably prudent manner, which asks the jury to “balance what the designer or manufacturer knew or should have known about the likelihood and severity of potential harm from the product against the burden of taking safety measures to reduce or avoid the harm.” Id. “Whether a manufacturer knew or should have known of a particular risk involves technical issues which do not easily admit to evidentiary proof and which lie beyond the comprehension of most jurors.” Id. (citing Peterson v. Safway Steel Scaffolds Co., 400 N.W.2d 909, 913 (S.D. 1987)). Further, expert testimony

may likely be essential to demonstrate causation: “[U]nless it is patently obvious that the accident would not have happened in the absence of a defect, a plaintiff cannot rely merely on the fact that an accident occurred. It is not within the common expertise of a jury to deduce merely from an accident and injury that a product was defectively designed.” Id. (citing Shaffer, 249 N.W.2d at 256); see also Engberg v. Ford Motor Co., 205 N.W.2d 104, 107 (S.D. 1973) (stating that plaintiff “was compelled to rely on the expert opinions” because “the circumstances of the accident precluded a direct determination of the cause or manner or the decedent’s death”); Presley v. Lakewood Eng. & Mfg. Co. 553 F.3d 638, 647 (8th Cir. 2009) (stating that the absence of expert testimony required summary judgment because plaintiffs could not demonstrate a genuine dispute of material fact with regard to causation on products liability claim). Expert testimony may also be necessary for Kendall to prove his four additional claims, particularly on the element of causation.

Although disputes of material facts are resolved against a party opposing a motion for summary judgment, “the question of admissibility of expert testimony is not such an issue of fact.” General Electric Co. v. Joiner, 522 U.S. 136, 142, 118 S. Ct. 512, 139 L. Ed. 2d 508 (1997). Accordingly, a court considering a motion for summary judgment may reject an expert's methodology if it is "fundamentally unsupported and therefore of no assistance to the trier of fact." Eckelkamp v. Beste, 315 F.3d 863, 868 (8th Cir. 2002). But a court may refuse to rule on the admissibility of expert testimony if the

record at the summary judgment stage is insufficient to make the determination of reliability and relevance required by Daubert and Federal Rule of Evidence 702. See Miller v. Baker Implement Co., 439 F.3d 407, 413 (8th Cir. 2006) (stating that a court may *sua sponte* consider the admissibility of expert testimony “so long as the court has an adequate record on which to base its ruling”).

B&L has not filed a specific motion to strike or exclude expert testimony or a motion for a Daubert determination. Instead, both parties have submitted many arguments on the question within their filings on the immediate motion for summary judgment. But despite the parties' vigorous arguments with regard to the admissibility of Hardten's testimony, the court has little other than those arguments to consider in evaluating the admissibility of Hardten's testimony under Daubert and Federal Rule of Evidence 702. Kendall has provided the court only with an affidavit from Dr. Hardten regarding his potential testimony, Docket 217-46, as well as a very brief discussion during Hardten's deposition regarding the basis for his conclusion that the blade used in Kendall's surgery caused DLK, Docket 213-23. These two documents are insufficient for the court to determine at this time the admissibility of Hardten's expert testimony. For example, B&L discusses a “two page report” from Hardten in its filings, but the court's search of the voluminous attachments to the parties' filings has not uncovered this report. See Docket 182, pages 14-15. While the court does not believe that Kendall is necessarily entitled to

more time to establish the admissibility of Hardten's testimony, see Miller, 439 F.3d at 412, neither is the court ready to make a Daubert determination regarding the reliability of this expert testimony given the current state of the record. See Anderson v. Hess Corp., 592 F. Supp. 2d 1174, 1181 (D.N.D. 2009). Therefore, the parties are instructed to supplement their previous submissions regarding Hardten's testimony with a copy of the two-page report and Hardten's deposition so the court can determine the reliability and relevance of Hardten's testimony in accordance with Federal Rule of Evidence 702.

**B. Strict Products Liability–Defective Design, Manufacture, and Warning**

In his complaint, Kendall alleges that “the surgical blades and their component parts were defective as to design, manufacture, and warnings, causing the surgical blades and their component parts to be in a dangerous and defective condition that made them unsafe for their intended use.” Docket 132 ¶ 21.

The South Dakota Supreme Court has adopted the Restatement (Second) Torts § 402A as the rule in strict liability situations. Engberg, 205 N.W.2d at 108-09. That provision states:

- (1) One who sells any product in a defective condition unreasonably dangerous to the user or consumer or to his property is subject to liability for physical harm thereby caused to the ultimate user or consumer, or to his property, if

- (a) the seller is engaged in the business of selling such a product, and
  - (b) it is expected to and does reach the user or consumer without substantial changes in the condition in which it is sold.
- (2) The rule stated in Subsection (1) applies although
  - (a) the seller has exercised all possible care in the preparation and sale of his product, and
  - (b) the user or consumer has not bought the product from or entered into any contractual relation with the seller.

In strict products liability, “[t]hree broad classes of defects have emerged: manufacturing defects where individual products within a product line were improperly *constructed*, *design* defects involving the entire product line, and defect by *failure to properly warn* or instruct users of a products where such failure renders the product hazardous.” Peterson, 400 N.W.2d at 912. “The chief elements which a plaintiff must prove in a case involving strict liability in tort are: (1) the defective and unreasonably dangerous condition of the defendant’s product, including the defendant’s connection with the product, and (2) a causal connection between such condition and the plaintiff’s injuries or damages.” Brech, 698 F.2d at 333-34 (citing Fajardo v. Cammack, 322 N.W.2d 873, 876 (S.D. 1982)); see also Engberg, 205 N.W.2d at 107 (stating that “[b]efore there could be a recovery under any of the three theories of products liability, the plaintiff had the burden of proving that the product was defective” and that the defect was the proximate cause of the injury).



## **1. Defective Design and Manufacture**

As noted above, an improperly designed product involves the entire product line, while a manufacturing defect involves “individual products within a product line [which] are improperly constructed.” Peterson, 400 N.W.2d at 912; see also White v. Cooper Indus., Inc. 2009 WL 234347, \*10 (D.S.D. Jan. 29, 2009) (manufacturing defect). “Strict liability arises when a manufacturer ‘sells any product in a defective condition unreasonably dangerous to the user or consumer.’ ” Burley, 737 N.W.2d at 408 (citation omitted). The plaintiff is not required to prove that the defendants knew or should have known of the defective nature of the product. Id. Rather, “[i]t is the unreasonableness of the condition of the product, not of the conduct of the defendant, that creates liability.” Id.

In its motion for summary judgment, B&L contends that Kendall cannot demonstrate that there is a dispute of material fact regarding the existence of a defect, in order to avoid summary judgment. Docket 182, pages 15-17. As stated above, the general rule is that the existence of a defect may be proven by direct or by circumstantial evidence, and a circumstantial case, by itself, is not a bar to a jury determination. Multiple pieces of evidence support Kendall’s claim that a defect in the blade’s design or manufacture caused his injuries, rendering summary judgment inappropriate. First, it appears that Kendall’s LASIK surgery was relatively routine with no notable problems until the DLK diagnosis. Second, DLK is a known risk of LASIK surgery. Additionally, in the

days and weeks prior to Kendall's surgery, B&L became aware of abnormally high instances of DLK in surgeries using blades from lot #517984. The DLK diagnoses were confined to various locations that used blades from the same lot, which was unusual and notable to B&L. Next, the extraordinarily high incidence of DLK from surgeries involving blade lot #517984 was unprecedented to B&L. Further, because of the high rates of DLK occurrences after surgeries using blades from this lot, LVCI and B&L took steps, prior to Kendall's surgery, to limit the number of blades from lot #517984 that were distributed and used. But B&L chose not to notify surgeons who already possessed blades from lot #517984 of the significant increase in DLK, at least not prior to Kendall's surgery. Finally, B&L saw instances of DLK decrease after blades in lot #517984 were no longer used.

In its argument, B&L cites the Restatement (Third) Torts, Products Liability § 3, and argues that Kendall must prove that "(1) the harm is the kind that ordinarily occurs as a result of a product defect and (2) the harm was not, in plaintiff's particular case, the result of causes other than the alleged product defect that existed at the time of sale or distribution." Docket 182, pages 15-16. The South Dakota Supreme Court has adopted the Restatement (Second) Torts § 402A as the law in strict products liability cases. Engberg v. Ford Motor Co., 205 N.W.2d 104, 109-09 (S.D. 1973). The South Dakota Supreme Court has never adopted the Restatement (Third) Torts, Products Liability. However, even if it were to apply Restatement (Third) Torts, Products Liability §

3, the court believes, for the reasons stated above, that there are genuine disputes of material fact as to whether the harm is of the kind that ordinarily occurs from such a defect, and whether the harm was the result of other causes. Thus, the court need not at this time determine whether Restatement (Second) Torts or (Third) Torts applies.

The admissible evidence offered by Kendall demonstrates that there are genuine disputes of material fact as to B&L's liability for a design and manufacturing defect. Thus, summary judgment on Kendall's defective design and defective manufacture claims is denied.

## **2. Failure to Warn**

In failure to warn strict liability claims, the issue is "whether the manufacturer's failure to adequately warn rendered the product unreasonably dangerous without regard to the reasonableness of the failure to warn judged by negligence standards." Burley, 737 N.W.2d at 409 (citation omitted). Plaintiff need not prove that the product itself was defective. Instead, " 'where a manufacturer or seller has reason to anticipate that danger may result from a particular use of [the] product, and [the manufacturer] fails to give adequate warning of such a danger, the product sold without such a warning is in a defective condition within the strict liability doctrine.' " Id. (citing Jahnig, 283 N.W.2d at 560)).

B&L argues that it is entitled to summary judgment because Kendall cannot, as a matter of law, establish a genuine dispute of material fact with

regard to the foreseeability of his injuries. Specifically, B&L argues that “[t]he law simply does not impose this liability on product manufacturers” to prevent DLK when “the medical community does not know what causes it” and where “there are too many surgical variables.” Docket 182, page 18.

While ordinarily strict products liability claims do not require the plaintiff to demonstrate that defendant acted improperly, failure to warn cases are different. Peterson, 400 N.W.2d at 912. To prove a defect through inadequate warnings, a plaintiff, instead of establishing the existence of a defect, must first establish a duty to warn. See id. (stating that “an otherwise properly manufactured and well-designed product may be found to be defective without an adequate warning”). In failure to warn cases, the factfinder must find the existence of a duty to warn by considering what the defendant knew or reasonably should have known about the product and the risk of injury. McElhaney v. Eli Lilly & Co., 575 F. Supp. 228, 232 (D.S.D. 1983) (citing to the comments in Restatement (Second) Torts § 402A); see also Burley, 737 N.W.2d at 409; Peterson, 400 N.W.2d at 913 (stating that a strict liability action “relieves the plaintiff of the burden of proving negligence by the manufacturer” but that in duty to warn situations a manufacturer may have a duty “to warn of dangers involved in a use which can be reasonably anticipated”). Consequently, the foreseeability of the injury is a necessary inquiry in determining whether a defendant breached its duty to warn.

A clear dispute of material fact exists with regard to the B&L's ability to foresee the potential of injury to Kendall. B&L was aware of a significant increase in DLK diagnoses in surgeries involving blades similar to the one used in Kendall's surgery, and it knew that additional blades from lot #517984 had been sold for use in future surgeries. B&L argues that a manufacturer cannot be liable for dangers it could not possibly have anticipated, and that is clearly the law in South Dakota. See Peterson, 578 N.W.2d at 593 (quoting 57A Am. Jur. 2d *Negligence* § 138 in stating that "[r]easonable foresight, rather than prophetic vision, is the law's standard"). But there are sufficient facts in dispute here about whether or not B&L could actually have foreseen Kendall's injuries given its knowledge at the time of his surgery on December 10, 2002.<sup>2</sup> Additionally, genuine disputes of material fact exist as to whether B&L's failure to warn rendered the blade unreasonably dangerous and whether it contributed to Kendall's injuries.

In his opposition to B&L's motion for summary judgment, Kendall cites Restatement (Third) Torts, Products Liability § 10 as the rule in failure to warn claims. Docket 218, page 15. Even though it was promulgated in 1998, the South Dakota Supreme Court has never applied the Restatement (Third) Torts, Products Liability, nor do the South Dakota Pattern Jury Instructions refer to it. In Robinson v. Brandtjen & Kluge, Inc., 2006 WL 2796252, \*6 (D.S.D. Sept.

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<sup>2</sup> The court does not decide at this time whether Kendall's other claims include a foreseeability element, as this has not been argued by either party.

27, 2006), however, the district court found that the Eighth Circuit decision in Novak v. Navistar Int'l Transp. Corp., 46 F.3d 844, 850 (8th Cir. 1995) was “persuasive authority predicting that the South Dakota Supreme Court would adopt the third Restatement regarding a post-sale duty to warn.” The court need not decide today whether Restatement (Second) Torts or (Third) Torts applies, because even if the court did apply Restatement (Third) Torts § 10, genuine issues of material fact exist which would preclude an award of summary judgment for B&L.

Restatement (Third) Torts, Products Liability § 10 provides:

- (a) One engaged in the business of selling or otherwise distributing products is subject to liability for harm to persons or property caused by the seller’s failure to provide a warning after the time of sale or distribution of a product if a reasonable person in the seller’s position would provide such a warning.
- (b) A reasonable person in the seller’s position would provide a warning after the time of sale if:
  - (1) the seller knows or reasonably should know that the product poses a substantial risk of harm to persons or property; and
  - (2) those to whom a warning might be provided can be identified and can reasonably be assumed to be unaware of the risk of harm; and
  - (3) a warning can be effectively communicated to and acted on by those to whom a warning might be provided; and
  - (4) the risk of harm is sufficiently great to justify the burden of providing a warning.

This provision “specifically injects negligence principles into strict products liability” actions. DeSantis v. Frick Co., 745 A.2d 624, 631 (Pa. Super. 1999) (declining to adopt § 10); see also Robinson v. Brandtjen & Kluge, Inc., 500 F.3d 691, 697 (8th Cir. 2007) (viewing § 10 as a provision concerning negligent post-sale failure to warn). “In deciding whether a claim based on breach of a post-sale duty to warn should reach the trier of fact, the court must determine whether the requirements in Subsections (b)(1) through (4) are supported by proof. The legal standard is whether a reasonable person would provide a post-sale warning.” Id. at comment *a*. Although “the particular circumstances of a case may permit a trial court to utilize the [Restatement’s four] factors to determine as a matter of law no duty existed [ , n]ormally . . . the jury determines whether a warning of a product danger should have been given” under the Restatement. Lovick v. Wil-Rich, 588 N.W.2d 688, 696 (Iowa 1999) (adopting Restatement (Third) Torts, Products Liability § 10 as the law in Iowa); see also Robinson, 500 F.3d at 697 (affirming summary judgment for defendants on § 10 failure to warn claim when there was no dispute that there was a post-sale warning campaign and that buyer received notice of the warning); Liriano v. Hobart Corp., 700 N.E.2d 303, 309 (N.Y. 1998) (adopting § 10 and citing to it in stating that “[f]ailure-to-warn liability is intensely fact-specific”).

Genuine disputes of material fact exist as to whether B&L incurred a duty to warn under Restatement (Third) Torts, Products Liability § 10. There is

a genuine dispute of fact as to whether B&L knew or should have known of a “substantial risk of harm” from use of blades from lot #517984, and whether the “risk of harm [was] sufficiently great to justify the burden of providing a warning.” Restatement (Third) Torts, Products Liability § 10(b)(1), (4).

Additionally, there is factual support for the conclusion that B&L could identify those who should be warned, that those receiving warnings would have been unaware of the risk of harm, and that a warning could have been effectively communicated and acted upon. Because genuine disputes of material facts exist, the court cannot conclude that B&L would be entitled to judgment as a matter of law under Restatement (Third) Torts, Products Liability § 10.

Accordingly, even if this court were to apply the Restatement (Third) Torts, summary judgment for B&L would still be denied.

For all of these reasons, the court denies B&L’s motion for summary judgment on Kendall’s failure to warn strict liability claim.

### **C. Negligence**

Kendall’s second cause of action alleges that B&L had a duty to “properly and safely design, manufacture, construct, assemble, test, inspect, maintain, sterilize, package, distribute, and sell” surgical blades; that it breached this duty “in that the blades were contaminated and not sterile” and were “dangerous and unsafe for their intended uses”; and that he suffered damages as a result. Docket 132 ¶¶ 25-29.



“To establish liability in negligence for defective product design or manufacture, a plaintiff must show that the defendant failed to use the amount of care in designing or manufacturing the product that a reasonably careful designer or manufacturer would use in similar circumstances to avoid exposing others to a foreseeable risk of harm.” Burley, 737 N.W.2d at 407 (citing Restatement (Second) Torts § 395). “To determine whether the designer or manufacturer used reasonable care, one must balance what the designer or manufacturer knew or should have known about the likelihood and severity of potential harm from the product against the burden of taking safety measures to reduce or avoid the harm.” Id. A plaintiff alleging negligent failure to warn must prove that

(1) the manufacturer knew or reasonably should have known that the product was dangerous or was likely to be dangerous when used in a reasonably foreseeable manner; (2) the manufacturer knew or reasonably should have known that users would not realize the danger; (3) that the manufacturer failed to exercise reasonable care and adequately warn of the danger or instruct on the safe use of the product; (4) that a reasonable manufacturer under the same or similar circumstances would have warned of the danger or instructed on the safe use of the product; (5) that the claimant was harmed; and (6) that the manufacturer’s failure to warn or instruct was a proximate or legal cause of the claimant’s injury.

Id. at 410 (citing Restatement (Second) Torts § 388 and Jahnig, 283 N.W.2d at 560). As with strict liability actions discussed above, a plaintiff bringing a negligence products liability action under South Dakota law may prove the

presence of a defect through circumstantial evidence. Shaffer, 249 N.W.2d at 256.

In its motion for summary judgment, B&L couches its challenges to Kendall's negligence claims in terms of the foreseeability of the harm. In negligence claims in South Dakota, foreseeability is both an element of the existence of a duty and of proximate cause. Peterson v. Spink Elec. Coop., Inc., 578 N.W.2d 589, 592 (S.D. 1998).

### **1. Existence of a Duty**

To be liable under a negligence theory, plaintiff must establish that “a relationship exists between the parties such that the law will impose upon the defendant a legal obligation of reasonable conduct for the benefit of the plaintiff.” Estate of Shuck v. Perkins County, 577 N.W.2d 584, 586 (S.D. 1998). A court examining the existence of a duty is to look to the foreseeability of the harm at the time when the act or omission occurred. Spink Elec. Coop., Inc., 578 N.W.2d at 592 (citing Poelstra v. Basin Elec. Power Coop., 545 N.W.2d 823, 827 (S.D. 1996)); see also Estate of Shuck, 577 N.W.2d at 588 (stating that there was no breach of a duty when defendant “could not have reasonably foreseen” the injury); Small v. McKennan Hospital, 437 N.W.2d 194, 200 (S.D. 1989) (concluding that foreseeability determination properly went to jury). Such a determination requires the court to look at the circumstances and knowledge B&L possessed in the time prior to Kendall's surgery. See Peterson, 578 N.W.2d at 592.

The court believes that a dispute of material facts exists as to whether B&L could have foreseen that its acts up until Kendall's surgery may have endangered Kendall, such that it owed him a duty to act with reasonable care. Kendall has presented evidence that B&L should have foreseen that inaction on its part would risk incidences of DLK in individuals like Kendall, who were operated on using blades from lot #517984. As the court cannot conclude as a matter of law that B&L owed no duty to Kendall, summary judgment on this ground is denied.

## **2. Causation**

Foreseeability is also an essential element in Kendall's burden to prove causation. Zarecky v. Thompson, 634 N.W.2d 311, 316 (S.D. 2001). "For proximate cause to exist, the harm suffered must be found to be a foreseeable consequence of the act complained of." Id.; see also S.D. Pattern Jury Instruction 20-10-20. Foreseeability, as it relates to a plaintiff's burden to show that defendant's conduct was a proximate cause of his injury, is to be evaluated at the time when the damage was done. Peterson, 578 N.W.23d at 592. Finally, "[c]ausation is usually a fact question for the fact finder except when there are no differences of opinion on the interpretation of the facts." Estate of Gaspar v. Vogt, Brown & Merry, 670 N.W.2d 918, 921 (S.D. 2003).

B&L argues that Kendall is unable to assert a triable question of fact as to whether the blade was the proximate cause of his injuries, asserting that Kendall cannot demonstrate that the blade was a "substantial factor" in

producing his harm. The “substantial factor” language has been used by South Dakota courts in reference to negligence actions. This test is discussed in the Restatement (Second) Torts § 433 and was adopted by the South Dakota Supreme Court in Mulder v. Tague, 186 N.W.2d 884, 887 (1971). It states that, to be actionable, negligent conduct must be a substantial factor in producing the harm. Mulder, 186 N.W.2d at 887. In other words, legal causation cannot be established when a defendant’s actions are “at the most remote and insignificant causative factors.” Musch v. H-D Coop., Inc., 487 N.W.2d 623, 625 (S.D. 1992) (quoting Mulder, 186 N.W.2d at 887). Use of the substantial factor determination, however, was called into question in Musch when the South Dakota Supreme Court said it preferred a “foreseeability approach” in determining proximate cause instead of the substantial factor language adopted in Mulder. Id. at 626. Regardless of this preference, after Musch the South Dakota Supreme Court approved trial courts’ use of the substantial factor language in questions of proximate cause. See Kostel v. Schwartz, 756 N.W.2d 363, 384-85 (S.D. 2008) (medical malpractice case); Smith ex rel. Ross v. Lagow Const. & Developing Co., 642 N.W.2d 187, 194 (S.D. 2002); Thompson v. Summers, 567 N.W.2d 387, 394 (S.D. 1997).

Under either the substantial factor test or the foreseeability test, the court finds that there is a question of material fact on the issue of proximate cause and that summary judgment must therefore be denied. Despite the multifactorial nature of DLK, a dispute of material fact exists as to whether

B&L's conduct in manufacturing the AccuGlide blade used in Kendall's surgery or in failing to warn Kendall or his doctor of potential complications of DLK was a substantial factor in Kendall's injuries, and whether Kendall's injuries were foreseeable to B&L prior to his injury. Because there is a difference of opinion as to the interpretation of the known facts, summary judgment is denied. See Thompson, 567 N.W.2d at 394 (stating that "questions of proximate cause are for the jury in 'all but the rarest of cases' ").

For the reasons stated above, Kendall has demonstrated a genuine dispute of material fact with regard to his negligence claim, such that there are questions of fact for the jury that preclude a finding by this court in B&L's favor. Therefore, B&L's motion for summary judgment is denied with regard to Kendall's negligence claim.

**D. Breach of Warranty and Negligent Infliction of Emotional Distress Claims**

B&L next argues that Kendall's claims for breach of express and implied warranties must be dismissed because they "suffer from the same infirmities as Kendall's claim for strict liability and negligence." Docket 182, page 22. B&L also urges the court to dismiss Kendall's claim of negligent infliction of emotional distress because he cannot prove either negligence or causation. Id. at 22-23. B&L has given the court no additional reasons why summary judgment on these claims is warranted.

This court has found that genuine disputes of material facts exist regarding Kendall's strict liability and negligence claims, precluding an award

of summary judgment to B&L. Because the court does not believe that there are infirmities which doom the negligence and strict liability claims, it similarly does not believe that summary judgment is appropriate on the remaining claims of breach of warranty and negligent infliction of emotional distress.

#### **E. Punitive Damages**

Finally, B&L argues that summary judgment on Kendall's claims for punitive damages is required, stating that there are “no proof of scienter” which supports the award of punitive damages. Docket 182, pages 23-24. SDCL 21-3-2 authorizes awards of punitive damages in tort “where the defendant has been guilty of oppression, fraud, or malice, actual or presumed.” “Active malice is a positive state of mind, evidenced by the positive desire and intention to injure another, actuated by hatred or ill-will toward that person.” Dahl v. Sittner, 474 N.W.2d 897, 900 (S.D. 1991). The court does not believe that any of the facts alleged by Kendall would support a finding of actual malice, as he has not asserted that B&L acted with an evil intent toward himself or other customers.

In contrast, presumed malice does not require that Kendall prove hatred or ill will. Instead, “[l]egal malice may be imputed to an act if the person acts willfully or wantonly to the injury of the other in reckless disregard of the other's rights.” South Dakota Pattern Civil Instructions § 35-02; see also Biegler v. American Family Mut. Ins. Co., 621 N.W.2d 592, 605 (S.D. 2001); Vilhauer v. Horsemens’ Sports, Inc., 598 N.W.2d 525, 530 (S.D. 1999) (stating

that “since 1877 this jurisdiction has allowed recovery of punitive damages for wanton and willful conduct and not mere negligence”). Willful and wanton misconduct is when a person acts or fails to act when the person knows, or should have known, that injury is likely to occur. Holzer v. Dakota Speedway, Inc., 610 N.W.2d 787, 793 (S.D. 2000); Case v. Murdock, 488 N.W.2d 885, 891 (S.D. 1992). The South Dakota Supreme Court has stated that presumed malice “implies that the act complained of was conceived in the spirit of mischief or of criminal indifference to civil obligations.” Dahl, 474 N.W.2d at 900 (citations omitted). Said another way, “South Dakota requires more egregious conduct than states which merely require proof of gross negligence and states which require proof of conduct more egregious than gross negligence, but which do not require proof of malice. Thus, South Dakota is among the states having the most stringent conduct requirement.” Bierle v. Liberty Mutual Ins. Co., 792 F. Supp. 687, 692 (D.S.D. 1992) (citation omitted).

The South Dakota Supreme Court addressed the issue of punitive damages in a products liability situation in Holmes v. Wegman Oil Co., 492 N.W.2d 107 (S.D. 1992). In that case involving claims of fraudulent concealment, punitive damages were awarded by the jury and approved on appeal when the manufacturer recalled a defective water heater ten years after it learned of a potential danger of explosion from a defective knob. Id. at 112-13. While the court’s survey of South Dakota cases approving punitive damages finds that most cases involve affirmative acts of fraud or deceit, on at

least one occasion the South Dakota Supreme Court has affirmed an award of punitive damages in an apparent negligence case. Flockhart v. Wyant, 467 N.W.2d 473 (S.D. 1991) (involving defendant who drove a vehicle with a blood alcohol content of 0.30% and had five prior convictions for alcohol-related offenses); see also Boomsma v. Dakota, Minnesota & Eastern R.R. Corp., 651 N.W.2d 238, 39-40 (S.D. 2002) (stating that submission of punitive damages instruction to jury in negligence case was not error, and even if it was error, it was not prejudicial); cf. Kostel v. Schwartz, 756 N.W.2d 363, 390 (S.D. 2008) (finding that while there was sufficient evidence to support jury finding of negligence, there were insufficient facts to justify punitive damages jury instruction).

Viewing the facts in the light most favorable to Kendall, the court concludes that summary judgment for B&L on Kendall's punitive damages request is required. Kendall alleges that B&L knew that there was a much higher incidence of DLK from surgeries using blades from lot #517984 than it had ever seen. Kendall also contends that, while B&L did take some steps to address customer complaints, its delay in responding to the DLK complaints meant that it did not inform Dr. Bormes of the risk of DLK occurrence from surgeries using blades from lot #517984, even though it presumably knew that Dr. Bormes (or, alternatively, LVCI) possessed blades from that lot and would likely use them in future LASIK surgeries. The court does not believe that these facts, even if true, constitute the requisite state of mind required by



SDCL 21-3-2 to permit jury consideration of Kendall's punitive damages claim. While B&L may be liable for its conduct in producing a defective product or failing to warn of possible defects, no conduct alleged by Kendall rises to the level of actual or presumed malice or wilful and wanton conduct. Therefore, summary judgment is granted on Kendall's punitive damages claim.

**F. Cross Claims by LVCI**

In its motion for summary judgment, B&L also argues in support of dismissal of LVCI's cross-claims against it. Docket 181. B&L does not address specifically LVCI's cross-claims; instead, B&L refers to them in combination with Kendall's claims in its arguments that it cannot be liable under the allegations in the complaint. See Docket 182. As the court determines here that summary judgment is not warranted on Kendall's claims against B&L, it similarly finds that summary judgment on LVCI's cross-claims against B&L is also not permitted.

**CONCLUSION**

For the reasons stated above, B&L's motion for summary judgment is denied with regard to Kendall's claims of strict liability, negligence, express warranty, implied warranty, and negligent infliction of emotional distress, and with regard to dismissal of LVCI's cross-claims. B&L's motion for summary judgment is granted with regard to Kendall's claims for punitive damages.

Accordingly, it is hereby

ORDERED that B&L's motion to strike (Docket 233) is denied.

IT IS FURTHER ORDERED that B&L's motion for summary judgment (Docket 181) is hereby granted in part and denied in part in accordance with this order.

Dated June 17, 2009.

BY THE COURT:

/s/ *Karen E. Schreier*

KAREN E. SCHREIER  
CHIEF JUDGE